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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,126	10/04/2005	Koji Sode	3691-0114PUS1	9547

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	01/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/02/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/520,126	SODE, KOJI	
	Examiner	Art Unit	
	Mohammad Meah	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/3/05, 6/6/06, 1/3/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

With preliminary amendment of this application, the applicant, on date 10/26/2006 elected with traverse Group I (claims 1-5 and 24-25).

Election/Restriction

During preliminary amendment of this application, the applicant on 05/08/2006 elected with traverse Group I (claims 1-5 and 24-25), drawn to modified PQQ glucose dehydrogenase comprising SEQ ID NO: 1, wherein position 192 of SEQID NO: 1 are replaced, for examination.

Groups II-VIII (claims 6-23) of election/restriction-office action of date 06/25/2006 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Applicants argument that as entire application presents a modified PQQGDH and therefore be examined entirely or more specifically all claims in groups I-IV and VI be examined is not persuasive because as explained in the election /restriction office action applicants modified PQQGDH (specially claim 1) lack special technical feature as defined by PCT Rule 13.2, because it does not claim a feature, which defines a contribution over the prior art. The lack of unity determination is still deemed proper and is therefore made FINAL.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 07/02/2003 in Japan # PCT/JP03/08418 and foreign application JAPAN 2002-196177 07/04/2002, JAPAN 2003-71760 03/17/2003.

Claim Objections

Claims 1-5, 24-25 are objected for containing non-elected subject matters.

Appropriate correction is required.

Claim Rejections

35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out

And distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-5 are rejected because of the amino acid position Nos in the claims and specification do not match with the amino acid position Nos in the SEQ ID NO: 1 in the sequence listing which makes all claimed inventions indefinite and confusing. Position 192 in SEQ ID NO: 1 is actually Tyr not Gln. **Is "Gln192 recited in claims" Gln168 in the SEQ ID NO: 1?**

The recitation in claim 2 "in a region of 186-206 amino acid of water soluble PQQGDH derived from *Acinebacter calcoaceticus*" is confusing as it is unclear if claim is limited to mutants of *Acinebacter calcoaceticus* PQQGDH and it is unclear as written that the number refer to amino acid positions that are mutated. It can be made clear by reciting "wherein one or more of amino acid residues 186-206 of--"

Claims 2 and 3 recite amino acid positions "186-206 or "192", without the corresponding sequence identifier number or SEQ ID NO. The claims are therefore indefinite

Claim 2, line 3- recitation of " or in an equivalent region" makes the claim indefinite because it is not clear what this equivalent region is or does it follow a numbering system?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to water soluble modified pyrroloquinoline quinine glucose dehydrogenase (PQQGDH) from any source or that derived from *Acinetobacter calcoaceticus* wherein any amino acid residue from region "186-206" of PQQGDH or residue "192" are modified and without the corresponding amino acid sequence. The specification teaches the structure of SEQ ID NO: 1 of only a single representative species of glucose dehydrogenase and variants thereof. However, the specification fails to describe other representative species by any identifying characteristics or properties other than high selectivity for glucose. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1-3 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for modified PQQGDH of SEQ ID NO: 1 wherein Gln192 is replaced by other amino acids, does not reasonably provide enablement for any modified

PQQGDH derived from any source or *Acinetobacter calcoaceticus* PQQGDH wherein any amino acid is modified from amino acid residue from region 186-206 and have greater affinity for glucose. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-3 and 24-25 are so broad as to encompass any PQQGDH derived from any source or *Acinetobacter calcoaceticus* wherein any amino acid is modified from amino acid residue from region 186-206 and have greater selectivity for glucose. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of PQQGDH variants broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of only a few PQQGDH variants.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art

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would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification while describe the mutation of two amino acid residues (i.e. Gln168 (or Tyr192?) and Asp167 (Asp143)) from 186-206 amino acid residues of SEQ ID NO: 1 does not support the broad scope of the claims which encompass any PQQGDH) derived from any source or *Acinetobacter calcoaceticus* wherein an amino acid is modified from region 186-206 of any PQQGDH sequence because the specification does not establish: (A) structure of PQQH protein wherein region 186-206 of PQQGDH sequence be modified to the attain desired selectivity for glucose ; (B) the general tolerance of PQQGDH to modification of region 186-206 of the PQQGDH sequence and extent of such tolerance; (C) a rational and predictable scheme for modifying any residue from region 186-206 of the PQQGDH sequence with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any PQQGDH) derived from any source or *Acinetobacter calcoaceticus* wherein any amino acid is modified from amino acid residue from region 186-206 and have greater selectivity for glucose. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of PQQGDH variants, having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is

unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir,1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

Recombinant Enzymes, 3C31 Remsen Bld


TEKCHAND SAIDHA
PRIMARY EXAMINER

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400 Dulany Street, Alexandria, VA 22314

Telephone: 517-272-1261